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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,666	04/06/2001	Timothy J. Neuberger	365279-001	6738

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EXAMINER
KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
1614	13

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/827,666	NEUBERGER ET AL.	
	Examiner	Art Unit	
	Brian S Kwon	1614	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) *29-31,37-45 and 59-66* is/are withdrawn from consideration.

5)☒ Claim(s) *46-51 and 55-56* is/are allowable except for the compounds of formula I.

6)☒ Claim(s) *1-7,13-28,32,33,52-54,57 and 58* is/are rejected.

7)☒ Claim(s) *8-12 and 34-36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicants Response to Restriction Requirement Acknowledged

1. Applicants election with traverse the Group I-g, claims 1-18, 32-36 and 57-58, is acknowledged. Applicants traverse the restriction requirement on the grounds that there would be no burden in searching the entire groups. This argument is not persuasive, as claimed invention would be distinctive, each from the other for the reason of the record.

In response to the examiner's restriction requirement on subject matters disclosed in Groups I-g and I-h, applicants state that the search required in Group I-g would result in identification of identical subject matter covered in I-h, which read on methods for treating injury to neural tissue and methods of treating neurodegenerative diseases, since one primary aspect of the methods and compositions of the present invention are directed to the use of neural regenerative therapy as a means for repair of neural tissue and treatment of neurodegenerative diseases (page 4, lines 20 of Response filed 5/29/03). This argument is found persuasive. Therefore, Group I-g and Group I-h will conjoint together and claims 1-28, 32-36 and 46-58 will be examined to the extent that they read on the elected invention. Claims 29-31, 37-45 and 59-66 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claims, the requirement having been traversed in Paper No. 12.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-7, 13-28, 32-33, 52-54 and 57-58 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The present claims are drawn to (i) a method of promoting tissue regeneration or expression (claims 1-7, 13-18 and 32-33); (ii) a method for promoting increased neuronal function (claims 19-28); (iii) a method a method of treating a neurodegenrative condition or disease (claims 52-54); and (v) a method of promoting regeneration of cells (claims 57-58).

The instant specification discloses (I) in-vitro study testing the activity of N-[4-[(4-fluorophenyl)sulfonyl]phenyl]-acetamide in increasing neural expression of eNCAM, MAP II, beta-tubulin, nestin, NF and NF-PO4; (II) in vivo study testing the activity of N-[4-[(4-fluorophenyl)sulfonyl]phenyl]-acetamide in increasing the growth of neural cells; and (III) in-vivo study testing the efficacy of N-[4-[(4-fluorophenyl)sulfonyl]phenyl]-acetamide in spinal cord injury treatment wherein bone marrow cells of N-[4-[(4-fluorophenyl)sulfonyl]phenyl]-acetamide-treated donor animal are implanted at the site of spinal injury (page 28, line 3 thru page 31, line 28; Examples 1-4). The instant claimed invention appears to be entirely based on the activity of N-[4-[(4-fluorophenyl)sulfonyl]phenyl]-acetamide in promoting the growth of neural cells which is mediated through eNCAM, MAP II, beta-tubulin, nestin, NF and/or NF-PO4 expression and the administration of N-[4-[(4-fluorophenyl)sulfonyl]phenyl]-acetamide-treated bone marrow cells to the site of injury for the treatment of spinal cord injury.

As stated above, the specification provides sufficient disclosure with respect to the activity of the claimed compounds represented by formula II, namely N-[4-[(4-fluorophenyl)sulfonyl]phenyl]-acetamide in promoting neural regeneration or neural expression and the administration of bone marrow cells that have been treated with said compounds, namely N-[4-[(4-fluorophenyl)sulfonyl]phenyl]-acetamide, to the site of injury for the treatment of spinal cord injury by promoting neural regeneration or neural expression. However, the instant specification clearly do not provide an adequate representation regarding the activity of the claimed compounds in promoting regeneration of liver cell, pancreatic cell and muscle cell. In addition, the specification provides insufficient written description to support the genus encompassed by the claim. Furthermore, the instant specification provides insufficient written description for the instantly claimed method for promoting increased neuronal function after a decrease in neuronal function due to a trauma, an injury or a neurodegenerative disease or condition and for treating a neurodegenerative condition or disease. The specification fails to provide sufficient written description for the skilled artisan to determine that the regeneration of neural tissue would provide the claimed method of promoting increased neuronal function as well as the efficacy of the claimed compounds in treating a neurodegenerative condition or disease.

Vas-Cath Inc. Mahurkar, 19 USPQ2d 1111, makes clear the "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the activity of the claimed compounds (formula II) in promoting neural tissue regeneration or neural expression and the administration of bone marrow cells that have been treated with the claimed compounds (formula II) to the site of injury for the treatment of spinal cord injury (more broadly the activity of the claimed compounds in treating injury to neural tissue), the skilled artisan cannot envision that (i) whether liver cell, pancreatic cell and muscle cell (more broadly which cells) would be responded to the activity of claimed compounds; (ii) the instantly claimed method for promoting increased neuronal function; and (iii) the efficacy of the claimed compounds in the treatment of a neurodegenerative condition or disease. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966(1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614,*

1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Nair et al. (US 4965284).

Nair teaches the use of the claimed compounds including N-[4-[(4-fluorophenyl)sulfonyl]phenyl]-acetamide for stimulating the prolifeation and differentiation of blood cell progenitors in bone marrow of warm-blood animals (column 8, lines para. 1; claim 17).

Allowable Subject Matter

4. The following is a statement of reasons for the indication of allowable subject matter: The use of compounds represented by formula II, N-[4-[(4-fluorophenyl)sulfonyl]phenyl]-acetamide, as an immunomodulators for restoring immune function in cancer or for the treatment

of cancer are well known in the art (US 6290929; US 4532349; WO 2001083457). Durr et al., Recent Ad. Chemother., Proc. Int. Congr. Chemother., 14th, 1985, Volume Anticancer Sect. 2, 922-3 discloses the use of N-[4-[(4-fluorophenyl)sulfonyl]phenyl]-acetamide (CL 259,763) in protecting or accelerating the recovery of bone marrow following myelosuppression by cytotoxic drugs, an effect possibly mediated by colony-stimulating factor. Nair teaches the use of the claimed compounds including N-[4-[(4-fluorophenyl)sulfonyl]phenyl]-acetamide for stimulating the prolifeation and differentiation of blood cell progenitors in bone marrow of warm-blood animals. However, none of the prior art references teaches or suggests the use of said compounds for promoting neural tissue regeneration or neural expression mediated through eNCAM, MAP II, beta-tubulin, nestin, NF and NF-PO4 or for the treatment of injury to neural tissue resulting from spinal cord injury, excitotoxic agent, chemotherapy or radiation or surgery.

5. Claims 8-12 and 34-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and if canceling non-elected invention.

6. Claims 46-51 and 55-56 are allowable except for the compounds of formula I which has been withdrawn from further consideration by the examiner as being drawn to a non-elected with traverse in Paper No. 12. Applicant is requested to cancel non-elected invention.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600